

The Safer Delivery of Surgical Services Programme (S3): explaining its differential effectiveness and exploring implications for improving quality in complex systems

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Running head: 'Explaining S3's differential effectiveness'

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Mini-abstract

This paper uses qualitative methods to interrogate the results of the S3 programme, which found that combined interventions produce greater improvements in WHO checklist adherence and technical performance than single system- or culture-oriented interventions. Findings support the programme's hypothesis, but demonstrate important additional mechanisms by which the superior effectiveness of combined interventions was achieved.

Abstract

Objective

To investigate the challenges and opportunities encountered during a programme of surgical quality improvement interventions, and understand how these affected the relative success of different intervention strategies.

Summary background data

Understanding why and how improvement interventions work is vital for developing improvement science. The Safer Delivery of Surgical Services Programme (S3) of studies tested the proposition that a combination of interventions addressing culture and system is more likely to result in improvement than either approach alone. Quantitative results supported this theory. This qualitative study investigates why this happened, what aspects of the interventions and their implementation most affected improvement, and the implications for similar programmes.

24 *Methods*

25 Semi-structured interviews were conducted with hospital staff (23) and research team members (11)
26 involved in S3 studies. Analysis was based on the constant comparative method, with coding conducted
27 concurrently with data collection. Themes were identified and developed in relation to the programme
28 theory behind S3.

29 *Results*

30 We found evidence that the superior performance of combined-intervention over single intervention
31 arms related to greater awareness and ability to act —supporting the S3 hypothesis—but also noted
32 differences of implementation, not part of the S3 design, that seemed to amplify the difference. The
33 greater ambition and more sophisticated approach taken by staff in combined-intervention arms
34 resulted in them requesting more intensive expert support, and this seemed crucial in their success.
35 Contextual challenges common to all sites have potential implications for the replicability and
36 sustainability of the approach.

37 *Conclusions*

38 Our findings support the S3 hypothesis, triangulating with quantitative results and providing an
39 explanatory account that adds detail to the causal relationship between interventions and outcomes.
40 They also highlight the importance of implementation strategies, and of factors outside the control of
41 programme designers.

Introduction

Quality improvement (QI) work in healthcare has increased substantially in recent years,^{1,2} in response to widespread acknowledgement of iatrogenic injury. The results of such efforts have been mixed, however,³⁻⁵ and work to replicate and spread apparently successful initiatives has also often resulted in disappointment.⁶ The patchy success of improvement initiatives has prompted renewed interest in opening the 'black box' of QI interventions, to uncover how they work and why they flounder. QI interventions almost always fall into the category of 'complex interventions',⁷ with many active components that operate through social mechanisms. As such an understanding of how they are intended to work, and how they operate in practice, is crucial to developing and refining QI interventions, and replicating successful interventions in other contexts.⁸

The Safer Delivery of Surgical Services (S3) Programme was a series of studies examining different approaches to improving quality and safety in surgery. The S3 Programme hypothesised that combining interventions would be more effective than using a single approach, based on the '3D model' of safety in surgery.⁹ The 3D model theorises the causes of risk at the clinical-microsystem level in terms of three sets of causes: systems of work; workplace culture; and technology used to conduct work. Since these dimensions interact in unpredictable and multidirectional ways, external interventions directed at only one dimension may be attenuated by interactions with other dimensions. For example, if staff receive better teamwork training to improve culture, they may be more aware of safety issues but, forced to continue using a risky system, may be unable to reduce risk. Similarly, if staff are equipped with the practical means to reduce system risk (e.g. through standardisation or training in a quality-improvement methodology such as Lean), they may lack awareness and understanding of issues associated with the wider organisational culture and be unable to reap benefits. Accordingly, the 3D model suggests that interventions addressing two or more of the dimensions are more likely to be successful than those

addressing only one.⁹ S3 postulated that by combining approaches in this way, overall risk would be reduced, and posed the question: is a combination of system and culture interventions more successful than a single-dimension intervention?

S3 involved six before-and-after evaluations of different combinations of three interventions across five hospital sites (tertiary referral, teaching and district general hospital) (Table 1). Each consisted of two levels of intervention: (i) training staff in the specified approach(es), and in broader change management, during the baseline period (to maximise attendance theatres were closed or back-fill was negotiated with management); (ii) staff-led improvement projects, targeting areas identified by staff during training, supported by the S3 team. This participatory approach was premised on evidence that improvement is more likely to succeed and sustain when led by frontline staff.¹⁰ Interventions were assessed in terms of improvement in surgical processes (non-technical team skills; counts of 'glitches' in the course of operations; and compliance with the WHO's surgical safety checklist).

[TABLE 1 HERE]

A pooled analysis of change through time (difference-in-difference) in the single-intervention studies 1-3 compared to the combined-intervention studies 4 & 5 showed significantly better improvement in the combined-intervention studies in relation to glitch counts ($p<0.001$) and full compliance with the WHO checklist ($p<0.001$) (study 6 was excluded from this analysis as it used different outcome measures) (REFERENCE TO ACCOMPANYING PAPER). Thus the hypothesis underlying the S3 programme appears to be sustained. This paper offers a qualitative account of the programme and its implementation; opening the black box in order to cast light on exactly what features—beyond the high-level combination of interventions—underlie this outcome, and whether and how it might be replicated elsewhere.

Methods

Following Dixon-Woods et al.,⁸ we undertook retrospective semi-structured qualitative interviews with a range of participants involved in S3, including staff at the five hospitals and S3 programme researchers. Interviews took place in the second half of 2013, after the interventions had been completed, but prior to analysis of the quantitative data, so at the time participants (and researchers) were blinded to the outcomes of the studies and relative success of single- and combined-intervention approaches. Topic guides for staff and programme researchers were developed by LCF and GPM, and refined in the course of data collection¹¹ (see appendix 1 for the initially agreed topic guides). This covered areas such as frontline staff involvement and engagement in S3, facilitators and barriers to S3, the role of the research team, support required at the frontline for S3, leadership and sustainability. Hospital staff were chosen to reflect the mix of roles involved in S3 at the microsystem level (see table 2), based on identification of staff who were heavily involved in the projects or who were deemed important in facilitating or progressing the projects by members of the S3 programme team (PGM, LJM, ERR, SJN). Programme staff included were those involved in design and delivery of S3's training and support for staff-led projects (see table 2). The interviews were carried out by two members of the research team who had little involvement in the intervention arms of S3 (LCF, FES). All were audio-recorded and transcribed in full by LCF. Participants gave informed, written consent to participate. Ethical approval was granted by the Oxford A Ethics Committee (REC:09/H0604/39).

[TABLE 2 HERE]

Analysis was based on the constant-comparative method,¹¹ assisted by NVivo software. It was conducted concurrently with data collection to allow development of the topic guide. LCF generated open codes—basic 'units of meaning'—from the data, informed by both *a priori* categories developed prior to data collection (based in turn on the existing literature and on discussions within the research

team) and through more inductive analysis of the data. Data from interview transcripts were initially broken down into these open codes in the course of close reading and rereading by LCF. GPM also read the entire dataset independently, advising LCF on the level of coding, and verifying the open codes developed by checking them against sources. Following this, we undertook a phase of theoretical coding¹¹ in which open codes were combined, refined, disaggregated and adapted into broader themes that informed the presentation of findings below. This was led by LCF and further developed by GPM. Examples of major themes developed included: 'catalysing role of external team'; 'senior buy-in'; 'teams' capacity for change'; 'hierarchy and local leadership'; 'differential interest and capacity for system improvement'; and 'sustaining change post-S3'. Data under each of these themes were then explicitly and systematically compared according to whether they came from staff in single-intervention sites, staff in combined-observation sites, or S3 programme researchers, in order to develop propositions that might account for the differences between sites that had begun to emerge in quantitative analyses. Putative findings were then discussed and refined with the wider S3 team (PGM, LJM, ERR, SJN, FES), including researchers who had been directly involved in the intervention arms, through a joint meeting, telephone and e-mail conversations, in light of the quantitative analyses.

Findings

In total, 36 hospital staff and 12 programme staff were identified as potential participants. From these, 23 hospital staff and 11 programme staff were interviewed. We present our findings over three sections, structured explicitly in terms of our comparison of themes between single- and combined-intervention sites, and presented in a narrative format that melds our interpretations with extensive direct quotations from interviews to ensure transparency. First, we consider the characteristics of the single- and combined-intervention approaches that seemed consequential in giving rise to differential outcomes. Next, we note differences of implementation between single- and combined-intervention

132 sites, highlighting how these may also have contributed importantly to the divergence. Finally, we turn
133 our attention to the way the interventions across all sites interacted with their organisational contexts,
134 highlighting the implications of this for potential for replication elsewhere.

135 Quotations are labelled according to participant background (H for hospital staff; R for researcher),
136 professional affiliation, and whether they relate to single- (S) or combined-intervention (C) studies.

137 *The intervention as intended: advantages of addressing multiple aspects of safety*

138 The hypothesis underlying the S3 programme was that a combination of interventions would address
139 both staff's consciousness and understanding of patient-safety issues, and their ability to develop
140 plausible initiatives to address them. Our findings offer support for this theory. Evident in particular
141 from our interviews was a tangible difference between the nature and volume of improvement work
142 undertaken in single- and combined-intervention sites. Typically, the projects pursued in single-
143 intervention sites were quite narrow, and perhaps overly focused on issues with a rather indirect
144 connection to patient safety: for example, a project in study 2 (Lean only) intended to ensure the first
145 patient to theatre arrived on time:

146 "The biggest challenge I think that we felt was engaging with, getting the anaesthetists on
147 board... they didn't see the value in it I think and I think they probably felt there were so many
148 other inefficiencies in the day that trying to save ten minutes at the start of the day was neither
149 here nor there..." (H13-S, surgeon)

150 In contrast, in combined-intervention sites, projects were more ambitious, as well as greater in number.
151 Hospital staff and researchers on the programme alike acknowledged that the single-intervention sites'
152 projects left something to be desired: as R2 put it, "what they came up with was quite shallow-minded—
153 well not shallow-minded, that's the wrong word, but quite primitive maybe in its design." Testimony

from staff suggested that training based on just one approach to improvement left gaps in their knowledge and awareness, and ability to translate theory into action. In contrast, in the combined-intervention sites, interviews with staff suggested that they felt the training had offered not just understanding or skills in isolation, but a comprehensive understanding of the two and how they might relate to one another (Table 3).

[TABLE 3 HERE]

More broadly, there was also a notable difference in the attitude towards improvement displayed in single- and combined-intervention sites. Across all sites, participants attested to the barriers that had deterred engagement with improvement initiatives prior to S3: scepticism about initiatives driven from the top down or by external agencies; a degree of ‘learned helplessness’ that prevented staff from taking up the gauntlet of improvement themselves; even some complacency about current practice and consequent reluctance to embrace improvement. In single-intervention sites, these attitudes largely remained; in combined-intervention sites, however, there was a marked shift in many participants’ dispositions (Table 4).

[TABLE 4 HERE]

The experiences of staff, then, seemed to support S3’s hypothesis that a combination of approaches designed to address the multiple dimensions of improvement is more effective, and suggest that this was due to both the breadth of knowledge they offer, and the way this opened participants to the possibility of achieving real improvement. As we discuss next, however, the divergence between sites also appeared to relate to differences in S3’s implementation.

The intervention as delivered: augmenting the benefit of combined approaches?

By design, the S3 programme involved a similar approach in all six studies: training in the relevant

176 methodology/ies, identification by hospital teams of the safety issue to be addressed and the project to
177 be undertaken, and then delivery of the project by the hospital team, with support from S3 researchers.
178 Other than the quantity of training, the approach was to be identical. In practice, however, this was not
179 always the case. Rather, the support provided by S3 researchers in the combined-intervention studies
180 proved to be rather greater than in the single-intervention studies:

181 “They kept asking for more help and they clearly felt like they needed a lot of support. It was still
182 very much staff led I do think, but I do think S3 needed to put in a lot of time, a lot of support.”
183 (R10-C)

184 Two factors in particular seemed to contribute to this divergence in implementation. Firstly, it appeared
185 to be a direct consequence of the effectiveness of the combination of training in opening participants’
186 eyes to the multi-dimensional nature of patient safety. Becoming conversant with the complexity of the
187 issues they faced led participants to seek greater support. Secondly, it seemed to be a function of the
188 greater volume and ambition of projects undertaken in the combined-intervention studies. More
189 complex projects required hospital staff to seek ongoing support, further input, and clarification from
190 those they saw as experts in the three approaches:

191 “[I realised] that actually I know nothing about research and I have no practical skills for
192 implementing research.” (H18-C, nurse)

193 “People don’t understand what change is, what improvement culture is, what the tools are, how
194 to use the tools, how to think about things.” (H2-C, surgeon)

195 “I think probably most people think they’re better equipped than they in fact are. You know,
196 that they don’t understand the techniques and approaches that are available.” (R2-C)

197 To this extent, the extra support in the combined-intervention sites might be understood as a

198 consequence of the S3 intervention itself, albeit an indirect one.

199 Also evident from participants' testimony, however, was that the nature of the support provided in the
200 combined-intervention studies differed notably from the single-intervention sites. In single-intervention
201 sites, the support mentioned by participants was largely 'administrative', relating to issues such as co-
202 ordination of the project, collection of data, and recapping training. Participants in the combined-
203 intervention sites spoke of a much wider range of support from the programme team, including much
204 more specialist input around financial, motivational, communication and facilitative support. For
205 example, a key component of the ongoing involvement of S3 researchers in the combined-intervention
206 sites that was not discussed by single-intervention participants was a brokerage role, helping to promote
207 positive interaction and ease tension between the professional groups involved in the projects:

208 "One of the ward clerks [in study 6] keeps coming to us to sort issues out with the doctors
209 because he doesn't think that he can communicate with the doctors and so this feeling that we
210 can help bridge the gap between the different specialities or teams." (R10-C)

211 "The dynamic of the department and how to get the involvement of the various people through
212 the department, what the various agendas are. Although you kid yourself that you know what's
213 helpful to the nursing staff, or the OT or the physio, actually unless you have that forum to sit
214 down with them and them tell you they don't care what you do on this bit of the ward round
215 and actually what matters to them is this, you never know that, so that [support] is probably the
216 thing that's been most useful." (H19-C, surgeon)

217 In consequence, in the combined-intervention sites, the S3 team came to offer much more than just
218 administrative support: rather, they became an integral part of the projects, offering expert assistance
219 and facilitation to hospital-based leads:

220 “They are so engaged. It’s as if they are an internal component on the ward, which is by far in a
221 way the biggest difference to the outside companies and ideas we’ve had in the past, it’s really
222 not like working with outside companies.” (H18-C, nurse)

223 As with the extra quantity of support required in the combined-intervention sites, the different quality
224 of support here might be seen as a consequence of the more thoroughgoing, comprehensive projects
225 pursued. These findings do not negate the superior effectiveness of the combined-intervention
226 approach. However, this mechanism was not one that was originally anticipated in the programme
227 design of S3, and given its apparent significance in the improvements achieved, future work should
228 account explicitly for this component of the approach.

229 *The surgical context: consequences for sustainability and replication*

230 Beyond the intervention itself and its implementation, participants also highlighted broader challenges
231 relating to the surgical context, with important implications for the viability of developing a similar
232 improvement approach elsewhere.

233 Most notably, there was a sense from participants across the studies that S3 was not an intervention
234 they would have had the time or inclination to pursue without the external input of the S3 research
235 team. While the academic status of the S3 team seemed to command legitimacy among participants
236 (who compared S3 favourably to experiences with private-sector consultancies who had interfered with
237 work processes and failed to deliver improvement), several participants found the experimental
238 approach to change involved in developing staff-led projects—with its attendant frustrations when
239 things did not go right—frustrating: it was “an alien way to think for most people. [...] They don’t like the
240 idea you’re doing an experiment where they might be proven wrong” (R4). Many commented that
241 pressures on their time were such that they had not been able to engage with S3 fully; had they been
242 expected to run the programme themselves, without external support, they felt they would have

243 struggled:

244 “I don’t think I let [S3] impact upon my workload but as a result of which I had a lesser
245 involvement in it.” (H22-C, surgeon)

246 “We have our half-day a week that’s supposedly devoted to training which boils down to a
247 couple of hours which isn’t protected from the on-call, and I don’t think there’s a time in the
248 week to add quality improvement to that.” (H20-C, surgeon)

249 Similarly, it was not always easy for hospital staff or S3 researchers to engage all those with a stake in
250 improvement projects and achieve buy-in and co-ordination across affected groups. The level at which
251 S3 sought to intervene was that of the clinical microsystem—the group of interdependent frontline
252 clinical practitioners whose activities had a direct bearing on patient care. But members of these groups
253 did not always directly interact with one another, since they worked to different rotas and across a
254 range of spaces. Opportunities to work with all individuals within a microsystem were therefore sparse:

255 “In lots of work settings you have lots of routine work, and you can then carve out from the
256 routine bits of time for specific project work. In the hospital setting, the surgical settings, that is
257 much harder, actually just getting time for people to participate in things. I mean any time you
258 wanted to have a meeting, the chances of having all the people you really wanted there were
259 very low.” (R4)

260 In consequence, the co-ordinating role taken on by the S3 team across all sites, and the brokering role
261 between disparate groups taken on by researchers in the combined-intervention sites, was all the more
262 important. The prospect of achieving improvement across a microsystem without this resource seemed
263 doubtful.

264 The focus on the microsystem level was a deliberate component of the programme theory of S3: the

objective was to ensure that action was oriented towards problems with a clear impact on patient care, within the scope of control of frontline teams. Executive permission for S3 had been granted, but beyond this, across sites senior managerial involvement was limited. This led to concerns from some about the sustainability and spread of the changes achieved. Without the input of managers to embed change, small wins could easily be ceded, and there was agreement that many of the gains rested heavily on the efforts of one or two individuals, rather than having been 'systematised'. In combined-intervention sites, furthermore, some staff were pessimistic about the prospects for sustaining and continuing improvement once the S3 team, on whom they depended for facilitation and expert assistance, withdrew:

"I worry that it won't unless those others, those sort of previous things in some way can be put in place. You know, unless there's some kind of touch point to S3; that rather than it going away completely, that there's some kind of on-going support or education or something, periodic to kept prompting it in people's minds." (H19-C, surgeon)

"They [frontline staff] got really frustrated that we were stepping back. [...] at one of the [combined-intervention] training days we mentioned that we would be stepping back from the running of the research, from the running of their individual projects and they said, 'No don't'. We said, 'You will just have to ask us when you want our help', and they said, 'We want your help, please can you can continue working with us', which is really nice but it just demonstrates the level of support that they felt they needed." (R2)

Thus while as discussed above the combined-intervention studies seemed to have succeeded in overcoming improvement inertia, there was a risk that they had replaced learned helplessness with learned dependency.

More broadly, our findings suggest that while S3's focus on action at the microsystem level can achieve

success, the organisational context poses important challenges for sustainability and replicability. For stretched clinical teams who, in contrast to other high-risk industries, lack dedicated time for safety improvement,^{12,13} more active managerial support may be important, especially where external support is unavailable or is time-limited.

Discussion

Our study offers support for S3's hypothesis that addressing two or three dimensions of the 3D model⁹ is more likely to be successful in improving patient safety than addressing only one, adding qualitative detail to the pooled quantitative analysis reported alongside this paper. S3 theorised that integrating approaches based on teamwork and systems improvement would equip clinical staff with both understanding and skills relating to safety, increasing their ability to improve safety effectively. Our data offer direct support for this proposition. Previous studies of Lean-based system improvement approaches in healthcare have found that they are impeded by a tendency of frontline staff to conceive of Lean as a set of tools rather than a philosophy,¹⁴ and thus to focus on "narrow and often disjointed tasks at the department and ward level" rather than the 'big picture'.¹⁵ Our findings offer important evidence that one way of overcoming this is complementing the systems focus of Lean with a broader understanding of the contexts in which staff work and the nature of the challenges they face, as supplied by an intervention such as teamwork training.

But our findings also highlight the indirect effects of the combined interventions on the quantity and substance of support offered in combined-intervention sites, suggesting an important modification to S3's theory. It was not only the combination of approaches but also the extra support this necessitated that was important in combined-intervention sites. Reports of previous single-intervention studies have not found the need for extra support for clinical teams,^{4,16-18} suggesting that this may indeed be a consequence of the complication added by combined interventions, and participants' recognition of the

311 need for extra support. Our more general findings on the challenge posed by the surgical context reflect
312 those of other authors, who have highlighted how lack of senior support^{14,19} and the complexity of
313 clinical microsystems that are interdependent but not always well co-ordinated¹⁹⁻²² can stymie
314 improvement efforts. This indicates a need for care in the application of the S3 approach elsewhere,
315 particularly outside formal research contexts where resources for support may be fewer, and where the
316 expertise, legitimacy and neutral brokerage offered by an external team may not be available.

317 More broadly, our study adds to understanding of what has recently been labelled “the most knotty
318 problem in improvement science,”²³ the relationship between improvement interventions, their
319 implementation, and the context in which they are realised. It has long been recognised that the
320 effectiveness of all but the simplest of improvement interventions is highly dependent on the clinical
321 and organisational context.^{4,8,24} But this is not simply a matter of finding the ‘right’ context in which an
322 intervention will blossom²⁵: rather, the relationship between context and implementation is dynamic
323 and unpredictable. Our study demonstrates, however, that our analytical lens needs to focus not only on
324 context and implementation, but also on the intervention itself. As staff in the combined-intervention
325 sites increased their understanding of the challenges they faced, so they came to request further
326 implementation assistance from the S3 team. The scope of the intervention thus widened in these sites,
327 as S3 researchers took on increasingly crucial brokering and facilitation roles in helping staff maximise
328 the success of their projects. This should not be conceptualised in terms of (in)fidelity to the
329 intervention as originally planned, since S3 explicitly allowed (indeed encouraged) participating staff to
330 develop their own programmes of work, using the support of the S3 team as they chose. It does
331 however signal the need for careful attention to variations in the content of interventions themselves,
332 as well as their contextual surroundings and the approach taken to implementation, if we are to
333 understand fully the differential success of apparently similar interventions.²³

The findings also have important consequences for replication and generalisability of the S3 approach. While S3's focus on the clinical microsystem seems appropriate, and its success in improving safety-critical clinical processes is demonstrated by quantitative findings,²⁶⁻²⁸ a concern for many staff was the corrosive impact of organisational pressures on improvement, particularly in the longer term beyond the S3 intervention period. Some previous studies using a similar approach to S3 in terms of staff involvement and leadership have reported long-term sustainability,²⁹ but others identify the need for an organisation-wide culture of continuous improvement to achieve lasting effects.³⁰ Other studies have cited a lack of management involvement³¹ or changes in leadership³² as potentially impacting on the likelihood of greater outcome change, and the sustainability of change. Such findings suggest that a combined approach at the micro-level may not be sufficient, and that an aligned macro-level intervention should be considered. The reliance of staff on the S3 research team in the short term (particularly in the more successful combined-intervention sites), and the fears for the prospects of improvement in the longer term, both suggest that any organisation seeking to replicate S3 without external input must design the implementation strategy carefully to ensure adequate time and expertise for the work. The importance attached by clinical participants to the neutrality, expertise and ability to facilitate co-operation between sometimes fractious groups within the microsystem suggests there may also be an important place for dedicated improvement teams who can serve similar roles.

Limitations

This paper has important limitations. It draws on qualitative interviews undertaken after the completion of the S3 studies rather than on contemporaneous ethnography (cf. Dixon-Woods et al.⁸), and as such is subject to imperfect recollection and recall bias. This is mitigated by the fact that neither interviewers nor participants had knowledge of the results of the individual S3 studies or the pooled analysis at the time of the interviews, though their views will have been informed by their own experiences and local

measures. Another limitation is the fact that not all those targeted for interview participated in the study; 92% of S3 programme staff and 64% of hospital staff approached were interviewed. The principal reason for non-participation was lack of availability. There is also potential for bias in the prior views of the research team, in favour of the S3 hypothesis, which may have influenced topic guides, interviews and analysis. We sought to address this by engaging a collaborator not involved in S3 to lead this qualitative work (GPM), with data collection and analysis carried out by researchers not directly involved in S3's intervention arms (LCF and FES) and informed by a method that relies primarily on inductive rather than deductive coding and analysis. The qualitative work is also affected by the limitations of the wider S3 programme design, as a non-randomised, unblinded controlled before-and-after study.

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Table 1: Summary of the studies included in the S3 programme

Study		Rationale	Further information
1	Single-intervention controlled study involving an ergonomic systems approach to using Standardised Operating Procedures (SOPs)	To develop and test a redesigned system for work in and around theatre based on SOPs with a focus on improving safety and efficiency. Many High Reliability Organisations use formalised work systems with a highly standardised approach to tasks, characterised by a method and regular checks to ensure it is followed. Deviation from the standard method remains permissible, but needs to be justified by specific circumstances. Complex, high risk but essentially repetitive tasks such as operations may be done more reliably if this approach is adopted, and indeed many highly successful surgeons appear to have developed their own versions of this. Whilst SOPs alone may be useful, they may be more effective if staff also receive background training which explains to them why the SOPs are valuable, and enhances the communication and interaction between team members.	Morgan et al. ²⁶
2	Single-intervention controlled study involving Lean Process Engineering	To evaluate the use of the Lean process improvement method to facilitate improvements in safety in healthcare. Arguably, the most successful example of system redesign in industrial settings has been the Toyota Production System. Previous studies have observed a major reduction in the effectiveness of the intervention when support is withdrawn, and analysis suggested this was due to the lack of psychological “ownership” of the techniques trained by the teams. However, our previous work with Lean process improvement approaches improved processes and fostered local ownership and empowerment.	(submitted manuscript a)
3	Single-intervention controlled study involving teamwork training based on the Crew Resource Management (CRM) approach developed in	To evaluate the use of teamwork training techniques based on the aviation CRM model in improving safety in healthcare settings. Other industries have identified that training in teamwork reduces the likelihood of an organisational accident. From our previous work, teamwork training has been demonstrated to	Morgan et al. ²⁸

	aviation	improve teamwork among the teams investigated, increase the appearance of a safety culture within an organisation, and reduce the number of non-operative problems and events.	
4	Combined-intervention controlled study involving SOPs and CRM-based teamwork training	To determine whether these two different interventions enhance care process performance more when combined than either does separately. The two approaches are different but potentially complementary. Teamwork training should enhance interactions between team members, while training in SOPs should improve the pathways and systems of work used. Therefore, we should expect that the combination should be synergistic.	Morgan et al. ²⁷
5	Combined-intervention controlled study involving Lean and CRM-based teamwork training	To determine whether these two different interventions enhance care process performance more when combined than either does separately. The two approaches are different but potentially complementary. Teamwork training should enhance interactions between team members, while Lean process improvement should improve the pathways and systems of work used. Therefore, we should expect that the combination should be synergistic.	(submitted manuscript b)
6	Combined-intervention study involving SOPs, Lean and CRM-based teamwork training	To develop an effective intervention that encompasses the lessons learnt from the other interventions, and can improve safety outcomes for all areas in acute hospitals. Analysis of the effects of teamwork training, Lean process improvement and SOPs in operating theatres point to the potential for improving the safety and reliability of the surgical process. However, the effects of any single intervention may be masked if there are issues in other areas of the system. Therefore, an approach that would involve multiple aspects of the work process may be more beneficial. Methods of intervention and evaluation would however need to be adapted to the settings if used in other parts of hospitals.	(manuscript in preparation)

443 **Table 2: Roles of healthcare staff interviewed**

Single interventions (10)	• Surgeons (3) • Nurses (5) • Managers (2)
Combined interventions (13)	• Surgeons (6) • Anaesthetist (1) • Nurses (4) • Managers (2)
S3 team (11)	• Fieldworkers (9) (all involved in both single- and combined-intervention sites) • Investigators (2)

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Table 3: Staff experiences of training in single- and combined-intervention sites

Single-intervention sites	"I was expecting it to be about patient safety. Now I don't think it was anything to do with that. It was about time management." (H14-S, theatre manager) "The training days were good. I won't say a lot of it's been put into practice." (H10-S, nurse) "It didn't have any great impact on the way that I work." (H12-S, nurse)
Combined-intervention sites	"I've learned probably to think about things slightly differently when it comes to problem solving and like having different ideas and thinking slightly laterally." (H20-C, surgeon) "I hadn't really thought of doing it that way, I just thought going in there and just setting it up and you know. So yeah, it opened our minds a little bit to think, 'OK, well maybe we need to know that this is truly the issue that we need to deal with'." (H21-C, nurse) "Lean is just a set of tools: if you just apply the tools as a tool-head you won't get very far. But I think if you actually engender the culture in a way of thinking then you're much more likely to get longer-term change." (H3-C, surgeon)

450 **Table 4: Changes in staff attitudes in single- and combined-intervention sites**

Single-intervention sites	"I suppose, I think there's probably a measure of, what's the word, disillusionment, that it's always been like this and you can't, you know, you're not going to change it." (H13-S, surgeon) "They were pretty efficient to start with. [...] Not finding anything here to change, which you know, from a management perspective is really reassuring because it shows we were doing very well to start with." (H3-S, manager)
Combined-intervention sites	"It certainly made me more aware of the fact that we could make change and up until that point I think I had probably felt quite frustrated about not knowing how to make change. So yeah, the fact that things happened, whereas before things hadn't happened, was certainly kind of empowering, in the sense that it made you realise that change could happen." (H19-C, surgeon) "I think the S3 project was probably more positively received because it did look at actually identifying a response to the staff problems." (H18-C, nurse)

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